DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022468/S-001 **SUPPLEMENT APPROVAL**

Allos Therapeutics
Attention: Todd Marshall
11080 CirclePoint Road, Suite 200
Westminster, Colorado 80020-2778

Dear Mr. Marshall:

Please refer to your October 19, 2010, supplemental New Drug Application (sNDA), received October 20, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Folotyn™ (pralatrexate injection).

We acknowledge receipt of your submissions dated April 8 and April 23, 2010.

This "Prior Approval" supplemental new drug application proposes adding a Patient Package Insert (PPI).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 022468/S-001.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Allison Adams-McLean, Regulatory Project Manager at (301) 796-3996.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22468	SUPPL-1	ALLOS THERAPEUTICS INC	FOLOTYN

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L JUSTICE
04/26/2010